UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,451	12/30/2003	Michael J. Bonnette	PS/08-039	2401

21140 7590 12/18/2008

GREGORY L BRADLEY
MEDRAD INC
ONE MEDRAD DRIVE
INDIANOLA, PA 15051

EXAMINER	
COLELLO, ERIN L	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
12/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,451	BONNETTE ET AL.	
	Examiner	Art Unit	
	ERIN COLELLO	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15,17 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *21 November 2008; 21 November 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed on 19 November 2008. Claims 2 and 16 have been cancelled without prejudice. Claims 1, 3-15 and 17-18 will be prosecuted on the merits.

1. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 9, 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Douk et al. (2002/0151927)**.

Regarding claims 1, Douk discloses an apparatus for use in vascular procedures comprising: a. a tubular guidewire (Figure 5, (20)) having a proximal end, a distal ends, and a lumen; b. a control cable (Figure 5, (42)) having a proximal end and a distal end, the control cable being slidably disposed within the lumen of the tubular guidewire (Paragraphs [0018] and [0049]); and, c. a sheathless filter (Figure 5, (25)) being distally coupled to the control cable and proximally coupled to the tubular guidewire and being formed of resilient flexible members interlaced to form a tubular net therebetween (Figure 5, (25)), the sheathless filter being radially expandable in

response to displacement of the control cable relative to the tubular guidewire into a plurality of selectively deployable states inclusive of (I) an undeployed state in which the resilient flexible members lie generally parallel to a longitudinal axis of the control cable and tubular guidewire and (II) a fully deployed state in which the resilient flexible members are radially expanded from the longitudinal axis of the control cable and tubular guidewire to a diameter coincident with a diameter of a blood vessel when introduced thereinto and expanded therein (Figure 5; Paragraphs [0017] and [0018]) wherein the sheathless filter presents at least a convex primary filter surface to a flow of blood within the blood vessel (see paragraphs 17 and 18).

Douk fails to explicitly disclose a means for resisting displacement of the control cable in the specific embodiment referenced by the Examiner.

However, Douk does disclose a stop element in some of the embodiments to limit axial movement (Paragraph 19).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter assembly to include a resisting means to prevent overexpansion of the filter. Also, the Applicant has provided no advantage to the three claimed embodiments of the resisting means. Therefore, it would have been obvious to a person having ordinary skill in the art to interchange a tube, a clamp, and a stop.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means for resisting displacement of the control cable to be approximate the proximal end of the tubular guidewire, since it has

been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Regarding claim 9, Douk discloses that the resilient flexible members of the sheathless filter comprises a tubular braided wire framework; and, a filter mesh formed of nitinol wires co-braided with the wires of the tubular braided wire framework (Figure 5, select at least two wires that intersect each other and that is the tubular braided wire framework, the remaining wires are considered the filter mesh).

Regarding claim 12, Douk discloses that the sheathless filter includes means for visibly identifying the sheathless filter under fluoroscopy (Paragraph [0051]).

Regarding claim 13, Douk discloses that the sheathless filter includes a distal interior face presenting a concave secondary filter surface to the flow of blood within the blood vessel (Figure 5).

Regarding claim 14, Douk discloses that the proximal end of the tubular guidewire is free of mechanical connections and obstructions so as to enable the tubular guidewire to function as a conventional exchange guidewire while the sheathless filter is deployed (No mechanical connections disclosed, guidewire is disclosed as functioning like a conventional guidewire).

Regarding claim 15, Douk discloses all of the claimed limitations above but fails to explicitly disclose the outer diameter of the filter.

However, it is well known and within the purview of one having ordinary skill in the art to modify the size of filters to fit specific anatomical features. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention

was made to modify Douk's filter to have a maximum outer diameter as claimed. Such a modification would prevent a filter that is too large for the desired vessel from damaging the vessel upon expansion.

4. **Claims 3-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Douk et al. (2002/0151927)** in view of **Kusleika et al. (US 6,325,815).**

Douk discloses all of the claimed limitations above but fails to explicitly disclose a means for resisting displacement of the control cable.

However, Kusleika teaches the use of a stop to prevent overexpansion of the filter (Figure 1, (40)).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter assembly to include Kusleika's resisting means. Such a modification would prevent overexpansion of the filter. Also, the Applicant has provided no advantage to the three claimed embodiments of the resisting means. Therefore, it would have been obvious to a person having ordinary skill in the art to interchange a tube, a clamp, and a stop.

5. **Claims 3-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Douk et al. (2002/0151927)** in view of **Seguin et al. (US 6,562,058).**

Douk discloses all of the claimed limitations above but fails to explicitly disclose a means for resisting displacement of the control cable.

Seguin teaches a clamp device for controlling the movement of an actuating cable (Figs 8A-D).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter assembly to include Seguin's resisting means. Such a modification would prevent overexpansion of the filter. Also, the Applicant has provided no advantage to the three claimed embodiments of the resisting means. Therefore, it would have been obvious to a person having ordinary skill in the art to interchange a tube, a clamp, and a stop.

6. **Claims 6-8, 10, and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Douk et al. (2002/0151927)** in view of **Greenhalgh (US 6,364,895).**

Regarding claims 6-8 and 10-11, Douk discloses that the resilient flexible members of the sheathless filter comprise a tubular braided wire framework (Figure 5, (25)); wherein the tubular braided wire framework is constructed of biocompatible nitinol wire (Paragraph [0044]); wherein a distal end of the tubular braided wire framework is operably attached to the control cable and a proximal end of the tubular braided wire framework is operably attached to the tubular guidewire (Paragraphs [0017] and [0018]).

Douk fails to explicitly disclose a polymer fabric woven into the framework.

However, Greenhalgh teaches co-braiding metal wires and polymer yarns to form a filter structure (Column 5 Lines 25-48).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter to include Greenhalgh's filter mesh. Such a modification would allow for control over the porosity of the filter. Also,

modifying the pore size of the filter would have been obvious to a person having ordinary skill in the art to prevent particulates from escaping the filter. The Kusleika reference cited above notes that pore size should be between 20 and 1500 microns as desired (Column 4 Line 59).

7. **Claims 17 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Douk et al. (2002/0151927) in view of Gillick et al. (US 6,383,206).

Regarding claims 17 and 18, Douk discloses all of the claimed limitations above but fails to explicitly disclose the resilient flexible members abutting to prevent blood flow.

However, Gillick teaches the concept of a filter that prevents blood flow in one state (Column 4 Lines 5-8).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter to include Gillick's state. Such a modification would prevent blood flow through the filter until the filter is properly placed.

Also, modifying the pore size of the filter would have been obvious to a person having ordinary skill in the art to prevent particulates from escaping the filter. The Kusleika reference cited above notes that pore size should be between 20 and 1500 microns as desired (Column 4 Line 59).

Response to Arguments

8. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

/Erin Colello/
Examiner, Art Unit 3734